

REMARKS

This paper is responsive to the Office Action dated May 4, 2005. Claims 1-31 are pending in the application. Claims 12-21 have been indicated as allowable. Claims 1-9, 22-28, 30 and 31 were rejected. Claims 5, 10, 11 and 29 were objected to.

In the Office Action, Claims 1, 2, 8, 9, 22 and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hazard (USP 5,058,580). Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hazard. Claims 4, 6, 7, 23-28 and 31 were rejected under 35 U.S.C. § 103 as being unpatentable over Hazard in view of Roy (USP 6,135,110).

**Section 102(b) rejections.**

Claim 1 of the present application is directed to a tracheostomy tube comprising a hollow tubular body having a proximal end portion, a distal end portion and a curved portion intermediate said proximal and distal end portions. A flange is situated at the proximal end portion of the tracheostomy tube. The flange is capable of radial extension from the tube, and is manipulatable to selectively prevent said radial extension.

The Hazard patent is directed to a tracheostomy tube comprising a tubular cannula having a tapered distal end portion that forms a smooth transition insertion area. The distal end portion is beveled at one side to facilitate percutaneous insertion of the tracheostomy tube into a patient's trachea through a stoma in the neck between adjacent cartilages. The proximal end portion of the tube includes an *integrally molded* flexible neck flange 26. Flange 26 is used in conjunction with apertures 27 and a suitable strap to secure the tracheostomy tube 10 through the neck of the patient. The proximal end portion 16 also includes a 15 mm standard coupler 28 adapted to readily interconnect the tracheostomy tube to a respirator system. See, Col. 4, lines 43-50.

In support of the anticipation rejection in view of the Hazard patent, the Examiner stated that Hazard teaches a flange that is capable of radial extension, and that is manipulatable to selectively prevent radial extension. The Examiner further

stated that the flange has two end extensions (near reference object 27 in Fig. 1), that are capable of preventing radial extension.

In response, Applicants respectfully submit that the flange as depicted in Hazard is *integral* with the proximal end of the tube (Col. 4, line 44), and is not selectively manipulatable in the manner of the flange described in the present claim. As stated in the present application, (see, e.g., paragraphs [0031] and [0032]), the flange may be manipulated, such as by selectively removing the flange from the tracheostomy tube (see, e.g., Figs. 3 and 4), or by axially folding the flange against the body of the tube. A tracheostomy tube having a removable or foldable flange has a reduced effective diameter when compared to conventional tracheostomy tubes that have radially extending flanges, such as flange 26 in the Hazard patent. As a result, an introducer sheath can be readily withdrawn in an axial direction over a tracheostomy tube having a removed or folded flange, and is not hindered in such withdrawal by the presence of a radially-extending flange that may otherwise obstruct such withdrawal.

With respect to claim 2, the Examiner stated that the flange of Hazard is selectively attachable to the proximal portion to provide radial extension, and detachable "by removing a strap holding the flange to the tube ..." Applicants respectfully submit that the strap does not hold the flange to the tube, as stated by the Examiner, because the flange is integrally molded with the tube (Col. 4, line 44). Rather, the strap is used to secure the tracheostomy tube to the patient. Nothing in the Hazard patent teaches a flange that is selectively attachable to and detachable from the proximal portion of the tube.

Independent claim 22 is directed to a device for percutaneous insertion into the trachea of a patient comprising a tracheostomy tube having a longitudinal passageway therethrough. The distal end portion of the tracheostomy tube is percutaneously insertable into the trachea, and a proximal end portion is exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange attachable to the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea. A locking assembly is provided for locking the

tracheostomy tube to the dilator during insertion of said tracheostomy tube into the trachea.

First, Applicants submit that Hazard does not teach an arrangement wherein the tracheostomy tube has a radially extending flange attachable to the proximal end portion of the tracheostomy tube *after the distal end portion has been inserted into the trachea*. Rather, as stated, the flange in Hazard is integral with the tracheostomy tube. It is not added after the distal end portion has been inserted into the trachea.

Secondly, the Examiner stated that the Hazard device includes a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tube into the trachea. In support thereof, he cited reference object 37 in Fig. 1, and Col. 5, lines 20-25 of the specification. Upon review of the pertinent portions of the Hazard patent, Applicants respectfully dispute the characterization of reference object 37 as a "locking assembly", and the depictions in the patent specification as referring to such an assembly. Reference object 37 merely points to a flange portion that limits the depth to which the obturator can be inserted. There is no apparent locking action. In the present application, on the other hand, an actual locking assembly is provided. The locking assembly is discussed, among others, at paragraphs [0041] to [0044], and illustrated at Figs. 7-9. In the preferred embodiment shown, the locking mechanism comprises a stop mechanism 72, and a securement member 74 that engages with the stop mechanism. As illustrated, the stop mechanism is preferably an annular ring, and the securement member is preferably a rotatable securement cap. In the embodiment shown, the securement member includes screw threads or other attachment mechanism for locking the securement member to a complementary attachment site on the tracheostomy tube, such as collar 22. Thus, there is an actual "locking" action that takes place in the inventive device. No such action is observed in the cited portions of the Hazard disclosure.

Independent claim 30 is direct to a method of inserting a tracheostomy tube into the trachea of a patient. The method comprises the steps of providing a tracheostomy tube comprising a hollow tubular body having a longitudinal passageway therethrough, said tubular body having a distal end portion for insertion into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted, said tubular body further having a curved portion intermediate said proximal and distal end portions; inserting said distal end portion of said tubular

body into said trachea; trimming an excess portion of said proximal end portion of said tubular body; and engaging a flange with said tracheostomy tube at said proximal end portion of said tubular body. Although the Office Action recites that claim 30 is also subject to a 35 USC 102(b) rejection in view of Hazard, no support or discussion of this rejection appears to be present in the Office Action, and Applicants can find no basis for such a rejection. Most particularly, Applicants assert that at a minimum, Hazard does not teach the "trimming" and the "engaging" steps of the present claims. Applicants assume that the reference to claim 30 in the Office Action was entered in error, and therefore, offer no further comments on this possible rejection.

**Sec. 103(a) rejections.**

**Claim 3.** Claim 3 is dependent on claim 2, and includes the additional limitation that the flange is attachable to the tube by a snap-fit. In the Office Action, the Examiner stated that "Hazard's disclosure of a flange with a strap attachment is considered an equivalent structure capable of securing the flange to the tube." However, as stated previously, the Hazard flange is *integrally molded* with the tube. The strap described in Hazard is provided to strap the tracheostomy tube to the patient's neck. It does *not* secure the flange to the tube in the manner of the snap-fit of the present claim.

**Claims 4, 6, 7, 23-28 and 31.** Claim 4 is dependent on claim 3, and includes the further limitations that the hollow tubular body includes a collar at its proximal end, said collar having a groove, and wherein the flange includes a cut-away portion, wherein the cut-away portion and said groove are cooperatively sized and shaped to mate when the flange is attached to the tube. Since claim 4 is dependent on claim 3, it includes all the limitations of claim 3 including the limitation regarding a flange attachable to the tube by a snap-fit. The cited references, either individually or in combination, fail to teach or suggest this arrangement. Claim 6 is dependent on claim 4, and includes the further limitation that the collar is integral with the hollow tubular body. Claim 7 is also dependent on claim 4, and includes the further limitation that the collar includes one or more barbs for attaching the collar to the hollow tubular body. Since these claims are dependent on claim 4, they include all the limitations of claims 3 and 4 set forth above. The cited references, either individually or in

combination, fail to teach or suggest this arrangement. It is further noted that the snap-fit of Roy does not relate to snapping a flange to a tracheostomy tube. Rather, Roy teaches a pressure adjusting mechanism for fixedly mating an inner cannula to an outer cannula. Further, it is noted that the collar of Roy is coupled to the inner cannula, unlike the arrangement of the present invention wherein the collar is engaged with the tracheostomy tube.

Claims 23-28 are dependent, directly or indirectly, on claim 22 and include all of its limitations, including the limitation of a locking assembly for locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube. It is further noted that Roy fails to set forth a locking assembly as claimed. Accordingly, Applicants respectfully submit that the cited references, either individually or in combination, fail to teach or suggest the features of the present claims. Accordingly, Applicants submit that claims 23-28 are allowable for at least the same reasons that claim 22 is allowable.

Claim 31 is dependent on claim 30, and therefore includes all of its limitations. Applicants have reviewed the Office Action, and can find no explanation by the Examiner on the basis for the rejections of claims 30 and 31. Nonetheless, upon review of the cited references, Applicants assert that such claims are allowable over these references.

#### **Objections to Claims and Drawings.**

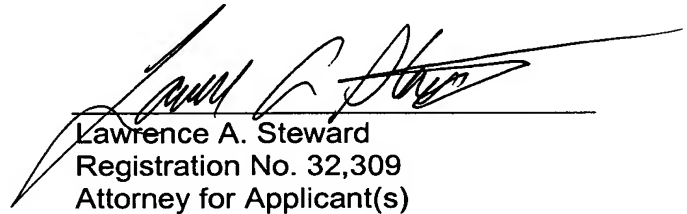
The Examiner objected to the drawings in the application on the basis that neither the "receptacle" in claim 5 nor the "cap" in claim 29 are shown in the drawings. The Examiner also objected to claims 5 and 29 on this basis.

Applicants respectfully assert that such elements are properly shown in the drawings, and that the terms in the claims are properly pointed out in the drawings. The receptacle referred to in claim 5 is shown as reference numeral 39 in Fig. 3. This element is discussed in the specification at paragraph [0031]. The "cap member having one or more screw threads" referred to in claim 29 is shown as reference numeral 74 in Figs. 7-9. This element is sometimes referred to in the specification as a "securement member", and at other times as a "securement cap". This is discussed in the specification at, among others, paragraph [0044].

**Conclusion.**

Based upon the foregoing, Applicants respectfully submit that all claims 1-31 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that any minor issues remain for resolution, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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